

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF
ILLINOIS EASTERN DIVISION**

**IN RE: ABBOTT LABORATORIES, ET
AL., PRETERM INFANT NUTRITION
PRODUCTS LIABILITY LITIGATION**

This Document Relates to:

ALL CASES

Case No. 1:22-cv-00071

MDL 3026

Hon. Rebecca R. Pallmeyer

**DEFENDANT MEAD JOHNSON'S OPPOSITION TO PLAINTIFFS'
OMNIBUS MOTION TO EXCLUDE CERTAIN PROPOSED EXPERT TESTIMONY**

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Plaintiffs' scattershot omnibus motion seeks to exclude five experts: three retained by Abbott and two retained by Mead Johnson—Dr. Erika Claud and Dr. Larry Hedges. But Plaintiffs' arguments miss the point of Rule 702: to ensure that the evidence the jury receives is from a qualified expert who is providing helpful opinions derived from a reliable methodology. Fed. R. Evid. 702; *see also In re Zimmer NexGen Knee Implant Prods. Liab. Litig.*, No. 12 C 2048, 2017 WL 36406, at *5 (N.D. Ill. Jan. 3, 2017) ("Under *Daubert*, the district court plays the role of gatekeeper and is responsible for determining whether the witness satisfies the Rule 702 factors—that is, whether the expert is qualified, whether the expert's methodology is reliable, and whether the testimony is relevant and will assist the trier of fact." (citation omitted)).

Plaintiffs do not argue Dr. Claud or Dr. Hedges are unqualified to offer their opinions. Nor could they. Dr. Claud is one of the preeminent NEC researchers in the country. She is the director of Neonatology Research and a Professor in Pediatrics at the University of Chicago Pritzker School of Medicine. As she testified, she has been writing, reviewing, and analyzing literature about NEC and its mechanism since she started practicing medicine—nearly three decades ago. She has received millions of dollars in government funding to study the mechanism of NEC—the same topic on which she intends to opine. And her theories and methods have been tested in the dozens of studies she has published in the peer review literature, which mirror the opinions she offers here. Similarly, Dr. Hedges is a biostatistician who wrote the book (multiple books) on statistical methods for meta-analysis. *See* ECF 612.2 (Hedges Expert Report) at 35–36. He has published hundreds of papers on statistical analyses and meta-analyses and presented at conferences all over the world. He is plainly qualified to conduct a meta-analysis and discuss its results with the jury.

Nor do Plaintiffs challenge the helpfulness of Dr. Claud's or Dr. Hedges's opinions. Dr. Claud, who, unlike Plaintiffs' experts, is an actual NEC researcher, offers opinions relating to the

mechanism of NEC. And Dr. Hedges provides an analysis of epidemiological literature comparing bovine-based nutrition products and human milk. Plainly, both these topics are relevant and helpful for a jury who needs to decide whether bovine-based formula causes NEC or whether it is due to something else entirely.

So Plaintiffs purport to attack the methodology of these witnesses. But there too, the arguments fall flat. In Dr. Claud's case, Plaintiffs ask the Court to ignore her nearly *three decades* of published research about the mechanism of NEC and conclude that Dr. Claud lacks a reliable basis for her opinions. That is unsupported by Rule 702. Dr. Claud's opinions and methods, which are the same in this Court and in her published work, have been examined and found reliable by the peer-reviewed literature and are straightforwardly admissible. And in Dr. Hedges's case, Plaintiffs focus on a purported "math error" and complain that he provided information at his deposition that they did not find in his report. Both are plainly fodder for cross and are not a basis to exclude Dr. Hedges's testimony.

The Court should deny Plaintiffs' motion in its entirety.

I. The Court Should Permit the Jury to Hear Erika Claud's Testimony.

Dr. Erika Claud is a renowned neonatologist with almost thirty years of research and clinical experience focused on NEC and intestinal immaturity in preterm infants. Plaintiffs seek to exclude Dr. Claud's opinions based solely on out-of-context deposition testimony purporting to show that Dr. Claud did not use a reliable methodology. Contrary to Plaintiffs' assertions, Dr. Claud employed the same methodology and intellectual rigor she uses in her research, including her published work. And based on a review of literature and decades of experience treating and researching NEC, Dr. Claud concluded—consistent with the peer-reviewed, published research she has performed throughout her career—that the development of NEC is likely caused by prematurity of the infant intestine, as influenced by factors including bacterial colonization, enteral

feeding, and exposure to the protective effects of human milk, rather than by infant nutrition products like formulas and fortifiers. Her opinions and methodology far exceed Rule 702’s requirements and the Court should deny Plaintiffs’ motion.

A. Dr. Claud Employed a Reliable Methodology Consistent with Her Real-World Practice.

In forming her conclusions in this case, Dr. Claud properly relied on decades of experience as a neonatologist and applied the same methodology she uses in her academic work. As an initial matter, Dr. Claud has studied NEC since she completed her neonatology fellowship in 1997. *See* Ex. 2, Claud Dep. 261:23-262:3; *see also In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 413 (S.D.N.Y. 2016) (“In certain fields, experience is the predominant, if not sole, basis for a great deal of reliable expert testimony.”) (citation omitted). Dr. Claud has been researching “issues related to feeding and to the possible differences between breast-fed and formula-fed infants” and “looking at intestinal immaturity” since the beginning of her career. Ex. 2, Claud Dep. 262:11–22. Indeed, in her first published paper, Dr. Claud concluded there was “evidence to support [the] hypothesis that intestinal injury in NEC may be the consequence of synergy of prematurity, enteral feeding, and bacterial colonization” and that breast milk is protective because it promotes maturation of the intestine. *See* Erika C. Claud & W. Allan Walker, *Hypothesis: inappropriate colonization of the premature intestine can cause neonatal necrotizing enterocolitis*, 15 The FASEB Journal 1398, 1401–02 (2001).

Since 2001, Dr. Claud’s scientific theories regarding NEC have been tested and subjected to peer review and publication time and time again, having been published in dozens of peer-reviewed and invited articles and book chapters over the last two decades. *See* Ex. 3, Claud Report at 45–76 (CV); *see also Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426, 431 (7th Cir. 2013) (citing *Daubert* reliability factors: “(1) whether the scientific theory or technique can be (and has

been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether a particular technique has a known potential rate of error; and (4) whether the theory or technique is generally accepted in the relevant scientific community.”). Moreover, Dr. Claud’s theories regarding NEC are “generally accepted” and, in fact, have been repeatedly re-affirmed by leading neonatologists and researchers focused on NEC. *See, e.g.,* Ex. 4, Necrotizing Enterocolitis (NEC) in Preterm Infants Working Group of the National Advisory Council of Child Health and Human Development (NACHHD), *Report to Sec’y, Dept. of Health & Human Svcs.* (Sept. 16, 2024) (detailing literature on state of science regarding NEC and feeding practices reviewed and concluding that exposure to formula does not increase risk of NEC); Ex. 5, FDA, CDC & NIH, *Consensus Statement on Recent Advisory Council Report on Premature Infants and Necrotizing Enterocolitis* at 2 (Oct. 3, 2024) (concluding that “[t]here is ***no conclusive evidence that preterm infant formula causes NEC***” and “there is strong evidence that ***human milk is protective against NEC***” (emphasis added)); *see also* *Schultz*, 721 F.3d at 431 (reliability under Rule 702 based in part on “whether the theory or technique is generally accepted in the relevant scientific community”).

In the face of Dr. Claud’s evident experience on this very subject, Plaintiffs argue that because Dr. Claud did not conduct a formal literature review in service of drafting her report, she did not employ an adequate methodology and her opinions are therefore unreliable. Not so. As a working scientist in this field (unlike Plaintiffs’ experts), over the last thirty years Dr. Claud has been “reading the literature, following along with the literature, and keeping up with the state of science on these issues.” Ex. 2, Claud Dep. 262:23–263:4. Indeed, the literature she has reviewed as part of her decades-long research and clinical experience was “the basis of [her] report.” Ex. 2, Claud Dep. 44:18–22. Moreover, despite her deep familiarity with this topic, Dr. Claud testified

that “[a]s part of this litigation, [she] re-reviewed a significant amount of literature associated with this topic” Ex. 2, Claud Dep. 44:23–45:1. And Dr. Claud did further research on “particular issues or articles that [she] thought would be useful for [her] report.” Ex. 2, Claud Dep. 263:23–264:2. Indeed, Dr. Claud cites and relies on numerous studies and data that provide further support for her conclusions. *See Manpower, Inc. v. Ins. Co. of Pennsylvania*, 732 F.3d 796, 809 (7th Cir. 2013) (finding that expert opinion was “reasoned and founded on data” and therefore not *ipse dixit*) (citation omitted). Ultimately, the principles and methodology Dr. Claud employed in forming her opinions “reflect reliable scientific practice.” *Schultz*, 721 F.3d at 431.

A methodology is simply a “framework” that an expert uses in reaching her opinions. *Manpower, Inc.*, 732 F.3d at 808. The methodology Dr. Claud used to prepare her report in this case—“describing the state of the literature, describing the studies involved, looking at particular articles to support particular points and offering [her] conclusions”—is the same framework she has employed throughout her academic career on this topic. Ex. 2, Claud Dep. 266:9–15; *id.* at 266:16–21 (“Q. Was there a way that you treated or assessed articles in putting your report together that is different or distinct from the way you review articles in putting together a published book chapter or review article? A. No.”). Such a methodology—which Dr. Claud applied with “‘the same level of intellectual rigor’ that [she] uses in [her] scientific practice”—more than surpasses Rule 702’s reliability requirements. *See Milward v. Acuity Specialty Prods. Grp., Inc.*, 639 F.3d 11, 19 (1st Cir. 2011) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)).

B. Dr. Claud Considered a Wide Breadth of Evidence to Support Her Conclusion.

Plaintiffs’ arguments that Dr. Claud ignored literature contrary to her conclusions and relied on sources she rejected outside of this litigation also fail.

First, Plaintiffs assert that Dr. Claud failed to consider materials that are contrary to her conclusion that formula does not cause NEC. That’s false. Though Plaintiffs point to one study they contend supports their assertions that formula causes NEC, which Dr. Claud did not cite in her report, *see* Ex. 6, Sarah N. Taylor et al., *Intestinal Permeability in Preterm Infants by Feeding Type: Mother’s Milk Versus Formula*, 4 Breastfeeding Medicine 11 (2009), Dr. Claud testified that she is “familiar with various literature in which [others] have hypothesized that elements of formula might injure the intestine.” Ex. 2, Claud Dep. 264:12–16. Indeed, Dr. Claud has cited and discussed that literature, *including Taylor (2009)*, in her published work. Ex. 2, Claud Dep. 264:17–20; *see also id.* at 274:17–276:2; Ex. 7, Elizabeth Humphrey & Erika Claud, *Impact of Microbes on the Intestinal Development of the Preterm Infant* in Mechanisms Underlying Host-Microbiome Interactions in Pathophysiology of Human Diseases 1, 18 (Jun Sun & Pradeep K. Dudeja eds., 2018) (“Furthermore, formula may negatively affect the immature gut epithelial border by increasing permeability, gut epithelial cell toxicity, and inflammatory responses[.]”) (citing Taylor (2009)). Dr. Claud’s ultimate rejection of the conclusions of those articles does not show that she failed to consider them. And in fact, Taylor (2009) concluded that “[p]reterm infant intestinal permeability was significantly decreased for those receiving human milk versus formula in a dose-related manner in the first postnatal month,” Ex. 6, Taylor (2009) at 11, which Dr. Claud testified was “consistent” with her opinions in this case and did not change her opinion “in any way.” Ex. 2, Claud Dep. 265:21–266:7.

In drafting her report, Dr. Claud chose to cite “references that [she] thought supported the specific point [she] was trying to make most clearly.” Ex. 2, Claud Dep., 267:14–16. However, in forming her opinions, she reviewed, relied on, and considered many articles aside from those specifically referenced, including the more than 150 articles and peer-reviewed publications on

her materials considered list, as well as her years of research and clinical experience. *See In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d at 421 (finding expert was qualified to provide opinions based on his “clinical and academic experience,” “decades of experiences as a doctor” and “review of scientific literature”). This is different from Drs. Sucre and Dr. Spector who have never previously researched NEC, were previously unfamiliar with the relevant literature, and failed to articulate a credible basis for why they chose to rely on certain materials while disregarding others. That Dr. Claud made an informed decision, based on her decades-long familiarity with the relevant body of literature, not to cite a particular article in her qualitative analysis does not warrant exclusion. Indeed, “lack of specific citation in [an expert’s] report goes to the weight of her opinions, not their admissibility.” *Id.* at 420.

Second, the Court should also reject Plaintiffs’ erroneous contention that Dr. Claud relied on sources that she “disavowed” outside of this litigation. Mot. at 8. They misstate her testimony. Plaintiffs point to one study cited in Dr. Claud’s report and argue that it contradicts a position she took in a book chapter she co-authored. In her report, Dr. Claud cites an article from 1975 for the proposition that osmolality of formula “has raised concerns for an increased risk of NEC.” Ex. 3, Claud Report, at 26. In a book chapter she co-authored in 2019, in summarizing the state of the knowledge at that time, she elaborated on the meaning of “has raised concerns,” noting that though osmolar formulas were “once thought to put a strain on the GI tract” of premature infants and increase injury, more recent research suggests otherwise. Ex. 2, Claud Dep. 165:15–167:16. This is a far cry from “disavowing” the article she relies on in her report, as Plaintiffs allege, nor does it constitute a methodological flaw warranting exclusion under Rule 702.

At bottom, Plaintiffs take issue with Dr. Claud’s conclusion that formula does not cause NEC, not her methodology or process for reaching that conclusion. This is not a proper basis for

exclusion. *See Schultz, LLC*, 721 F.3d at 431 (“Although [Rule 702] places the judge in the role of gatekeeper for expert testimony, the key to the gate is not the ultimate correctness of the expert’s conclusions. Instead, it is the soundness and care with which the expert arrived at her opinion: the inquiry must ‘focus . . . solely on principles and methodology, not on the conclusions they generate.’”) (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 595 (1993)). Therefore, the Court should deny Plaintiffs’ motion to exclude Dr. Claud’s opinions.

II. Dr. Hedges’s Methodology Is Reliable, and Plaintiffs’ Challenges Are Not Grounds for Exclusion.

The Court should deny Plaintiffs’ motion to exclude Mead Johnson’s biostatistician Dr. Larry Hedges,¹ as Dr. Hedges’s opinion is the product of reliable principles and methodology as required under Rule 702.

Plaintiffs ask this Court to throw out Dr. Hedges’s testimony and analysis based on what they contend are “grievous calculation errors that tilted his opinion in Mead’s favor and obscured his methodology.” Mot. at 2. In fact, it is only a single calculation with which Plaintiffs take issue. Specifically, Plaintiffs argue that Dr. Hedges miscalculated the risk ratio for the Sullivan study, a study that does not report a risk ratio. Mot. at 3. Separately, Plaintiffs contend that Dr. Hedges did not establish a methodology that can be replicated. Both arguments fail.

A. Dr. Hedges’s Purported “Math Error” Is Not Grounds for Exclusion.

Plaintiffs do not challenge the methodology by which Dr. Hedges performed his meta-analysis. Mot. at 3. *Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426, 431 (7th Cir. 2013) (“Although [Rule 702] places the judge in the role of gatekeeper for expert testimony, . . . the inquiry must ‘focus . . . solely on principles and methodology, not on the conclusions they

¹ Plaintiffs’ motion inaccurately refers to Dr. Hedges as an “epidemiologist.” Mot. at 2. Dr. Hedges is a biostatistician and has never claimed to be an epidemiologist.

generate.”) (quoting *Daubert*, 509 U.S. at 595) (emphasis added)). They do not, for example, challenge the relevance of meta-analyses generally nor do they challenge the Knapp-Hartung methodology Dr. Hedges employed. Instead, Plaintiffs focus on a single purported “math” and “data error.” Mot. at 4. Even if the number Dr. Hedges calculated for the Sullivan study were indicative of a flaw in Dr. Hedges’s analysis, courts have been clear that “[a] minor flaw in an expert’s reasoning or a slight modification of an otherwise reliable method does not render expert testimony inadmissible.” See, e.g., *Hardeman v. Monsanto Co.*, 997 F.3d 941, 962 (9th Cir. 2021) (explaining that “[i]mperfect application of methodology may not render expert testimony unreliable”) (internal quotation marks omitted); *Amorgianos v. Nat’l R.R. Passenger Corp.*, 303 F.3d 256, 267 (2d Cir. 2002) (same).

Such is the case here too. Plaintiffs are welcome to question Dr. Hedges about the Sullivan risk ratio in his report at trial, just as they did at his deposition, but exclusion of Dr. Hedges’s opinion on this basis is improper. *Manpower, Inc.*, 732 F.3d at 808 (“[T]he court’s role is generally limited to assessing the reliability of the methodology—the framework—of the expert’s analysis.”). As a last-ditch attempt, Plaintiffs argue that Dr. Hedges’s failure to amend or supplement his report renders his opinion inadmissible. Notably, Plaintiffs cite neither case law nor rule mandating this kind of amendment or supplementation. Plaintiffs will have the opportunity to cross examine Dr. Hedges at trial on the Sullivan study risk ratio.

B. Contrary to Plaintiffs’ Argument, Dr. Hedges Did Disclose a Methodology, and Plaintiffs Do Not Challenge It.

Plaintiffs then argue that the Court should exclude Dr. Hedges’s testimony because, according to Plaintiffs, he “failed to articulate *any* methodology.” Mot. at 4 (emphasis in original). More specifically, Plaintiffs argue that Dr. Hedges did not disclose the software package used to

conduct his analysis and did not provide the output or input data supporting his conclusion, which renders his opinion inadmissible. Mot. at 5.

But that’s wrong. Plaintiffs asked, and Dr. Hedges testified in depth, about the software package that he used in his analysis: Metafor for R. Ex. 1, Hedges Dep. 38:1–4, 74:13–25, 76:20–80:17. Dr. Hedges also made clear that the particular method of meta-analysis that he ran within Metafor for R was the Knapp-Hartung method. Ex. 1, Hedges Dep. 76:20–80:17. As noted above, Plaintiffs do not challenge Dr. Hedges’s use of Metafor, nor do Plaintiffs challenge the reliability of Knapp-Hartung as a method of meta-analysis. Further, contrary to Plaintiffs’ assertion, Dr. Hedges also described the inputs he used—namely, that for the randomized controlled trials core to his meta-analysis, his inputs included the “sample size in each group and the number of events in each group.” Ex. 1, Hedges Dep. 43:20–25. And when questioned on whether his results could be replicated, Dr. Hedges provided the name of the software package and made clear that “specify[ing] clearly enough the analysis that you did . . . [,] any software ought to give you the same answer, unless there is an error in the software.” Ex. 1, Hedges Dep. 42:12–24.

Thus, Plaintiffs are left challenging the completeness of Dr. Hedges’s expert report. *See* Mot. at 4. But “the purpose of expert reports is to eliminate unfair surprise.” *Gaines v. Chicago Bd. of Educ.*, 717 F. Supp. 3d 746, 770 (N.D. Ill. 2024). And Plaintiffs cannot pivot to arguing they were prejudiced by any allegedly incomplete report because Plaintiffs have affirmatively elicited the testimony they claimed was lacking. *In re Sulfuric Acid Antitrust Litig.*, 235 F.R.D. 646, 660 n.13 (N.D. Ill. 2006) (“[T]he very fact that the [plaintiffs] elicited such testimony at the deposition has been found, in other instances, to amount to all the disclosure necessary under Rules 26(a)(2) and 37(c)(1).”) (citation omitted); *see also Ollison v. Wexford Health Sources*, No. 17-1077, 2021 WL 11962562, at *2 (C.D. Ill. July 1, 2021) (noting that opinions expressed during

deposition “sufficiently eliminates any prejudice to the Plaintiff”); *Tate v. Lyle Ams. LLC v. Glatt Air Techs., Inc.*, No. 13-2037, 2016 WL 9711526, at *2 (C.D. Ill. June 6, 2016) (same).

Accordingly, for the reasons above, Defendants ask that the Court deny Plaintiffs’ motion to exclude Dr. Larry Hedges.

CONCLUSION

For the foregoing reasons, the Court should deny Plaintiffs’ motion to exclude the testimony by Mead Johnson experts Dr. Erika Claud and Dr. Larry Hedges.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing document was served upon counsel of record on March 14, 2025, via the Court's electronic filing system and via email for any material provisionally filed under seal.

/s/ Emily S. Ullman